UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	**Oral Argument Requested**

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO PARTIALLY EXCLUDE OPINIONS OF DEFENDANTS' CLASS CERTIFICATION EXPERT LAUREN J. STIROH, PH.D.

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PRELIMINARY STATEMENT

Dr. Lauren J. Stiroh, Ph.D., a Harvard-educated economist with decades of experience in the field of applied microeconomics, offers opinions to rebut the classwide damages model proposed by Plaintiffs' expert, Dr. Rena Conti, particularly Dr. Conti's flawed assumption that all of the valsartan-containing drugs ("VCDs") at issue in this case are economically worthless. Plaintiffs' motion to partially exclude Dr. Stiroh's testimony should be rejected for several reasons.

First, Plaintiffs contend that Dr. Stiroh's criticism of Dr. Conti's "worthlessness" theory is inadmissible because it is based on a "hypothetical," "counterfactual world." (Pls.' Br. at 1.) This mischaracterizes Dr. Stiroh's opinions. As Dr. Stiroh explained at her deposition, her opinions are premised on reliable factual and economic evidence that some, if not all, of the actual individuals who purchased and used VCDs received a therapeutic or other benefit from the medications. Any complaints Plaintiffs may have regarding Dr. Stiroh's interpretation of the evidence as it applies to the value of VCDs are matters for cross-examination, not bases to exclude her testimony.

Second, Plaintiffs' assertion that Dr. Stiroh should be barred from offering any opinions regarding the "therapeutic benefit that a patient might have received by consuming (i.e., ingesting) VCDs" because Plaintiffs allege that they were injured "at the point of sale" (Pls.' Br. at 2) is equally baseless. While Plaintiffs may allege

that VCDs were valueless at the time of sale, Defendants are entitled to contest that assertion with expert evidence that the value of a prescription medication (at any time) depends on the therapeutic benefits it provides and other individualized evidence. In addition, Plaintiffs' complaint that Dr. Stiroh has not designed an economic model to measure the value of VCDs in light of their therapeutic benefit ignores that she is a rebuttal expert and is entitled to critique Dr. Conti's damages model at the class certification stage without proffering one of her own (especially given her opinion that "[e]conomic loss damages to members of consumer or third-party payor ('TPP') classes, if any, cannot be assessed on a classwide basis using information and methods common to the proposed class"). (Expert Report of Lauren J. Stiroh, Ph.D. ("Stiroh Rep.") ¶ 7(i), Jan. 12, 2022 (Pls.' Br. Ex. 1).)

For all of these reasons, set forth in more detail below, Plaintiffs' motion to partially exclude Dr. Stiroh's opinions should be denied.[1]

[1] Plaintiffs have not challenged Dr. Stiroh's opinions that: (1) Dr. Conti's method for calculating economic losses does not account for the "financial positions" that the consumers and TPPs would have been in if the at-issue VCDs had never been sold or if patients purchased other treatments; (2) "Dr. Conti presents flawed methods for assessing damages for Retail Pharmacies and Wholesalers" that "ignore[] the complexities of the pharmaceutical supply chain"; and (3) Dr. Conti's method for calculating Wholesaler unjust enrichment damages fails to account for the "value to consumers" provided by the at-issue VCDs. (Stiroh Rep. ¶¶ 66, 74, 75.)

BACKGROUND

Dr. Stiroh has a Ph.D. in economics from Harvard University and serves as the Managing Director of NERA Economic Consulting ("NERA"). (Stiroh Rep. ¶¶ 1, 4.) During her 26-year tenure at NERA, Dr. Stiroh has provided economic consulting services and testimony in connection with liability, damages, and class certification issues. (*Id.* ¶ 2.) Based on her substantial experience and review of the record evidence in this case, Dr. Stiroh offers three main critiques of the damages model put forward by Plaintiffs and their expert, Dr. Conti. (*Id.* ¶ 6.)

First, Dr. Stiroh opines that Dr. Conti's proposed measure of damages is inaccurate and cannot be used to assess economic losses on a classwide basis because Dr. Conti makes no attempt to measure the value of VCDs to consumers using established economic methods. (*Id.* ¶ 73.) Instead, Dr. Conti simply asserts that any adulterated or misbranded drugs are worthless, without presenting any analysis or research to establish that consumers' views on product value are conditioned on FDA standards. (*Id.* ¶ 16.) As Dr. Stiroh explains:

> [Dr. Conti's] measure of value fails to perform an appropriate comparison of costs and benefits not only because she disregards the beneficial therapeutic effects of the at-issue VCDs, but also because her proposed damages methodology assumes worthlessness regardless of the degree of known or perceived health risks, if any, due to impurities. There is no basis, as a matter of economics, to assume that the value of a product is unrelated to the magnitude of its known or perceived risks and benefits, or that pills that pose a minimal risk to consumers/TPPs would have the same "assigned" value as pills that posed significant risks.

(*Id.* ¶ 20.) Dr. Stiroh further explains that the correct measure of "the economic value of a prescription drug depends on numerous factors requiring individualized analysis, including but not limited to the therapeutic value of the product's indicated use, the personal benefits to the consumer (patient) from the therapeutic value of the product, and the known or perceived risks." (*Id.* ¶ 7(ii).)

Second, Dr. Stiroh opines that Dr. Conti's method for calculating economic losses does not consider whether the proposed consumer or TPP class members actually experienced any financial losses. (*Id.* ¶ 74.) Specifically, Dr. Stiroh explains that Dr. Conti did not consider any scenarios where patients would have purchased alternative medications if Defendants' VCDs had been unavailable or the costs to consumers and insurers in such a scenario. (*Id.*) Based on a review of the price of VCDs and alternative medications before and after the recall, Dr. Stiroh concludes that "Plaintiffs would likely have spent at least as much on hypertension treatment had the at-issue VCDs never been sold, or had patients purchased other treatments." (*Id.*; *see also id.* ¶¶ 52-64.)

Finally, Dr. Stiroh opines that Dr. Conti's method for calculating unjust enrichment damages for the Retail Pharmacy and Wholesaler Defendants is flawed because, among other things, it ignores "the complexities of the pharmaceutical supply chain, contracting, and payment flows that would require individual inquiry to trace revenues and profits from sales to class members to each Defendant and an

analysis of the benefit conferred by a plaintiff to a particular defendant that would be unjust for the defendant to retain." (*Id.* ¶ 75.) Dr. Stiroh further explains that Dr. Conti has not demonstrated the feasibility of collecting the necessary data to properly account for all costs, and that for pharmacies, Dr. Conti's calculations do not correspond to profits because they do not consider appropriate costs. (*Id.* ¶¶ 65, 70, 75.)

ARGUMENT

The standard that applies to *Daubert* motions against a defense expert is set forth in Defendants' Opposition to Plaintiffs' Motion to Partially Exclude the Opinions of Timothy E. Kosty and is incorporated herein by reference. Plaintiffs do not come close to showing that Dr. Stiroh's opinions should be excluded under this standard.

I. DR. STIROH'S CRITIQUES OF DR. CONTI'S "WORTHLESSNESS" OPINIONS ARE RELIABLE AND ADMISSIBLE.

In forming her damages model, Dr. Conti takes the position that all of the at-issue VCDs were worthless because they contained impurities and therefore are adulterated and misbranded. (Expert Decl. of Rena Conti, Ph.D. ¶¶ 7, 8, 20, 42-46, Nov. 10, 2021 (Ex. 1).) Specifically, Dr. Conti opines that there is no legitimate supply curve for misbranded or adulterated drugs because they cannot be sold in the United States under FDA guidelines, and that misbranded or adulterated medications therefore have no market equilibrium price or economic value. (*Id.* ¶ 44.) Dr. Stiroh

challenges this assertion, explaining that it is improper to assume that the VCDs purchased and used by the proposed class members were worthless because some individuals who purchased the medication received a therapeutic value from it that may have outweighed any alleged risks, especially given the varying impurity content of the VCDs at issue. (Stiroh Rep. ¶¶ 7(i)-(vi), 20-29, 40-44.) Dr. Stiroh does not, as Plaintiffs contend, premise her criticisms of Dr. Conti on an "assumption that any class member might have purchased VCDs despite knowing about the adulteration or misbranding" or a "hypothetical, counter-factual world in which it was known to all that VCDs were adulterated or misbranded." (Pls.' Br. at 4-5.) To the contrary, Dr. Stiroh's opinion is factually grounded in the evidence in the record, which demonstrates that VCD users obtained valuable therapeutic benefits from the medications.

The record shows that 21 of the named plaintiffs in the proposed consumer economic loss class acknowledged at their depositions that VCDs were effective at managing their hypertension during the class period. (Stiroh Rep. ¶ 29.) Moreover, a number of the consumer named plaintiffs continued taking their VCDs after learning that they had been recalled, as recommended by the FDA. (*Id*. ¶¶ 29, 33, 34.)[2] And millions of people, including some of the consumer named plaintiffs,

[2] Plaintiffs assert in a footnote that this evidence is "not of any help to Dr. Stiroh for obvious reasons," but fail to identify those reasons or point to any countervailing *(cont'd)*

regularly pay for and consume products such as bacon that contain higher amounts of NDMA than the FDA's recommended recall limit for VCDs. (*Id.* ¶ 35.) Dr. Stiroh also notes that the assumption that patients will no longer value a product once its sale is barred within the United States is contrary to empirical evidence. (*Id.* ¶¶ 48, 49.) For example, Dr. Stiroh explains that patients choose to purchase or consume medications that are not FDA-approved, as well as products that have potential health risks similar to those alleged here. (*Id.* ¶¶ 30-39, 48, 49.)

Further, Dr. Stiroh made clear at her deposition that her opinions relate to the value of VCDs ***as purchased and used by the proposed consumer class members and the patients for whose prescriptions the proposed TPP class members paid*** and do not depend on any assumptions as to whether those individuals would have been able to purchase VCDs if they had been deemed adulterated. (*See* Dep. of Lauren J. Stiroh ("Stiroh Dep.") 76:22-77:11, Mar. 25, 2022 (Pls.' Br. Ex. 2) ("Q. If you were told to assume that adulterated drug products cannot be placed into the stream of commerce, would any of your opinions have changed? A. On a going-backward basis for considering the diminution of value, if any, for products that were consumed, that factor does not affect whether consumers obtained value for the product that they consumed, I have considered and described elsewhere in my report

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evidence that Plaintiffs or any other class member did not receive a therapeutic benefit from the VCDs. (Pls.' Br. at 1 n.1.)

a consideration of how to evaluate differences in financial outcomes for consumers if the products had not ever been available in the United States."); *see also id*. 185:5-186:2 (Dr. Stiroh testifying that it is her "opinion, as an economist, that whether there is supply of the Valsartan-containing drugs at issue or not, there is value that was received for the products that were purchased and consumed" and that she "disagree[s] with Dr. Conti that the absence of supply of certain Valsartan-containing drugs implies that the value of those products that were consumed by consumers is zero").) As Dr. Stiroh explained at her deposition:

> If the[] products at issue are found to be adulterated and misbranded, then, as I explained in my report, to an economist assessing diminution of value that comes from adulteration or misbranding, it matters the degree to which any product consumed by any consumer was adulterated or misbranded, the impact that that adulteration has for the efficacy of the drug for that consumer, whether it still has a therapeutic benefit to the consumer, the amount of the product that they consumed, the change in the risk profile for the consumer, and I understand that some of those factors depend on things individual to the consumer, such as their weight and health history.

(*Id*. 57:11-58:2.)

While Plaintiffs and Dr. Conti may disagree with Dr. Stiroh's opinion that the evidence in the record—and basic economic principles—demonstrate that proposed class members (or, in the case of the proposed TPP class, their subscribers) received value from consuming VCDs, such arguments go, at most, to the weight of Dr. Stiroh's opinions, not their admissibility. *See In re Fisher-Price Rock 'N Play Sleeper Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 1:19-md-2903, 2021 WL

4988186, at *7 (W.D.N.Y. Oct. 19, 2021) ("[T]here is a legitimate difference of opinion, both among judges and experts, about the significance of supply side information in calculating loss of value" and "[a] difference in opinion is not a basis for exclusion of an expert opinion under *Daubert* standards.").

Plaintiffs' authorities are not to the contrary. Plaintiffs cite *Mondis Technology Ltd. v. LG Electronics, Inc*. and *Apotex, Inc. v. Cephalon, Inc.* for the proposition that expert opinions that are "contrary to law or fact" or to the record are inadmissible. (*See* Pls.' Br. at 7.) But both of those cases excluded expert opinions offered by the party with the burden of proof because they were based on assumptions or theories that ***had previously been rejected or foreclosed by the court as a matter of law***. *See Mondis Tech.*, No. 15-4431 (SRC), 2021 WL 4077563, at *3 (D.N.J. Sept. 8, 2021) (excluding portion of supplemental expert report on damages submitted after a jury verdict in patent infringement case because it was based on a "built-in apportionment theory" that the court had already rejected in connection with a motion for a new trial on damages); *Apotex*, 321 F.R.D. 220, 235 (E.D. Pa. 2017) (excluding plaintiff's expert's damages calculation in an antitrust case because it was based on a theory of conspiracy between the defendants that the court had specifically rejected as a matter of law at the summary-judgment stage). Here, by contrast, whether the at-issue VCDs had value to the patients who

purchased and used the medications is an open question of fact on which the experts disagree—and that must be decided by the jury.[3]

This Court's motion-to-dismiss ruling does not change that result. At the motion-to-dismiss stage, the Court was required to "accept all factual allegations as true" and therefore merely determined that Plaintiffs' ***allegations*** of economic worthlessness were sufficient to state a claim, not that Plaintiffs had ***established*** worthlessness as a matter of law. *See In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, MDL No. 2875 (RBK-JS), 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021).

Likewise, neither Defendants nor their experts have the burden to prove that the VCDs received by the proposed class members or their subscribers had value

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[3] Plaintiffs' other cases are even farther afield. *See, e.g.*, *Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002) (***affirming admission*** of failure analysis expert's opinion that accident was caused by presence of hydraulic fluid inside the engine because "the record reflects sufficient evidence of hydraulic fluid solvent in places it should not have been—outside the engine, near the engine, and in the torquemeter housing—to form the factual foundation for [the expert's] testimony"); *Sec. & Exch. Comm'n v. Ambassador Advisors, LLC*, No. 5:20-cv-02274-JMG, 2021 WL 6052589, at *5 (E.D. Pa. Dec. 21, 2021) (excluding portions of law professor's opinions regarding defendant investment firm's regulatory compliance and inspection by the SEC as unreliable and lacking sufficient factual basis where the expert failed to perform an analysis for the firm's compliance history and knew little about the SEC inspection); *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 F. App'x 781, 791 (3d Cir. 2009) (excluding engineer's opinion that contractor defendants' failure to install a check value caused an industrial accident because uncontroverted evidence established that the check value had been installed).

that exceeded any risks of the medications. Dr. Stiroh is instead permitted to critique Dr. Conti's opinion that the proposed class members' damages equal the total cost paid for VCDs by challenging her assumption that those medications were economically worthless to all patients who used them. *See In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1368 (N.D. Fla. 2018) (a defense expert's "opinions properly may be limited to criticizing the analysis and conclusions presented by another party").

For these reasons, the Court should reject Plaintiffs' argument that Dr. Stiroh's criticisms of Dr. Conti's "worthlessness" theory are inadmissible.

II. DR. STIROH'S OPINION THAT VCD USERS RECEIVED BENEFITS FROM CONSUMED VCDS IS RELIABLE AND HELPFUL TO THE FINDER OF FACT.

Plaintiffs also argue that Dr. Stiroh's opinions regarding the health benefits of VCDs do not "fit" the facts of this case because: (1) such benefits are irrelevant to Plaintiffs' theory that consumers and TPPs were injured "at the point of sale"; (2) the therapeutic value of medications to users has no bearing on the TPPs' claims; and (3) Dr. Stiroh does not proffer a methodology for taking therapeutic value into account in determining damages. (Pls.' Br. at 8-9.) Each of these arguments is baseless.

First, Plaintiffs contend that any "therapeutic" or other benefits provided by the at-issue VCDs to consumers who used the medications is irrelevant to both the

"Consumer Economic Loss" and "TPP Plaintiffs" because they allege "that they suffered economic loss at the point of sale." (Pls.' Br. at 8.)[4] But courts have determined that a proper measure of damages in a case involving a prescription drug with allegedly undisclosed risks is "[t]he difference between what the plaintiff paid and the value of what the plaintiff received." *In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 131 (2009). As a result, determining damages requires "evidence of the actual value of what the plaintiff received," which necessarily includes the therapeutic value of the drug. *Id*. at 131, 135-36 (finding that plaintiffs asserting class claims on behalf of consumers and TPPs based on the allegation that they overpaid for a prescription drug that was withdrawn from the market could not "recover without first identifying a proper comparator drug," with an equal therapeutic value, "the cost of which would provide the actual value to the patient of the [medication] received"). Further, courts have noted that the question of whether a calculation of damages arising from the sale of a noncompliant medication should take into account the "therapeutic value . . . received . . . is necessarily a credibility

[4] This contention is inapplicable to Dr. Stiroh's opinions regarding Wholesaler unjust enrichment damages. With respect to Wholesalers, the economic harm *does not* occur at the "point of sale"—Wholesalers sell only to Pharmacies *in advance of* Consumer/TPP purchases. Even Plaintiffs' own damages expert, Dr. Conti, specifically testified that this "point of sale" theory applies to other Defendants, *but not to Wholesalers*. (Dep. of Rena Conti, Ph.D. 128:2-130:18, Feb. 11, 2022 (Ex. 2).)

dispute between the parties' experts" and "[r]esolution of this dispute is for the jury at trial." *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, 417 F. Supp. 3d 531, 557-58 (E.D. Pa. 2019).

There is also no merit to Plaintiffs' argument that the Court's finding that Plaintiffs adequately pled a cause of action at the motion-to-dismiss stage by alleging that "contaminated drugs are economically worthless at the point of sale" means that Defendants are precluded from disputing this theory by presenting evidence regarding the benefits provided by at-issue VCDs to the consumers who took them. (*See* Pls.' Br. at 8 n.19 (quoting *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, 2021 WL 222776, at *16).) As explained above and in Defendants' briefing in opposition to class certification, which is incorporated herein by reference, the Court's motion-to-dismiss order merely held that Plaintiffs' allegations, ***if accepted as true***, stated a claim. (*See* Defs.' Mem. in Opp'n to Pls.' Mot. for Class Cert. of Cons. Econ. Loss Claims at 61-62 (ECF 2008); Mfr. & Pharm. Defs.' Mem. in Supp. of Mot. to Exclude Ops. of Dr. Rena Conti at 14-16 (ECF 2040-1); Defs.' (Proposed) Surreply in Further Opp'n to Pls.' Mot. for Class Cert. of Third-Party Payor Claims at 1-2 (ECF 2069-1).) At the class certification stage, however, Defendants have a right to challenge such allegations with evidence—including expert testimony—that the at-issue VCDs had economic value in light of the health benefits the medication provided to users. (*Id.*)

Second, the Court should also reject Plaintiffs' separate argument that Dr. Stiroh purportedly admitted that the therapeutic value of VCDs is irrelevant to the proposed TPP class members' claims by agreeing that "the allegations of harm to the TPPs are not related to their consumption of the drug." (Pls.' Br. at 8 (quoting Stiroh Dep. 67:4-10).) Plaintiffs attempt to take a single line of Dr. Stiroh's testimony—which accepts the obvious point that insurance companies and other TPPs do not actually consume the prescription medications they pay for—and twist it into an admission that the value provided by VCDs to the TPP subscribers who consumed them has no bearing on the damages allegedly sustained by TPPs. That is not the case. Indeed, Dr. Stiroh explained at her deposition that her "consideration of economic harm includes a consideration of the difference between the price paid, which would be the price that was paid at retail, for example, for the products at issue, and the value received. And the value received would be the value that a patient who consumed the product received from consuming it." (Stiroh Dep. 68:6-13.) In other words, Dr. Stiroh opines that, because a TPP purchased VCDs on behalf of its plan participants, the value of the medications received depends on the benefit provided to those individuals. (*See* Stiroh Rep. ¶ 7(vii) ("[T]he at-issue VCDs provided value to TPPs because the at-issue VCDs continued to offer therapeutic value, and, as I understand, allowed the TPPs to provide the prescription

coverage for their members that they were contractually required to provide.").) This opinion is relevant and admissible for all the reasons set forth above.

Third, Plaintiffs' suggestion that Dr. Stiroh's opinions should be excluded because she has not provided a model for calculating the "diminution of value" of the at-issue VCDs that takes into account their therapeutic value (Pls.' Br. at 9) is similarly baseless. As noted above, it is *Plaintiffs'* burden to provide a damages model capable of calculating damages on a class-wide basis. "[D]efendants' experts have a less demanding task, since they have no burden to produce models or methods of their own; they need only attack those of plaintiffs' experts." *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 285 (E.D.N.Y. 2007); *see also Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 786 (3d Cir. 1996); *In re Abilify*, 299 F. Supp. 3d at 1368; *In re Aluminum Warehousing Antitrust Litig.*, 336 F.R.D. 5, 29-30 (S.D.N.Y. 2020); *In re Cessna 208 Series Aircraft Prods. Liab. Litig.*, No. 05-md-1721-KHV, 2009 WL 1649773, at *1 (D. Kan. June 9, 2009). This is particularly so because the gravamen of Dr. Stiroh's opinion is that one ***cannot*** construct a class-wide damages model in this circumstance. (*See, e.g.*, Stiroh Rep. ¶¶ 7(i), 7(iii), 7(v), 7(vii), 7(ix)(c)-(d); Stiroh Dep. 70:5-9.) Accordingly, Dr. Stiroh's report discusses in detail the types of information that would need to be considered in assessing the value of VCDs to a particular consumer and provides examples of how such characteristics vary among both the proposed class members and consumers generally. (Stiroh Rep.

¶¶ 28-44, 48-49.) This information provides a reliable foundation for Dr. Stiroh's critique of Dr. Conti's damages model.

CONCLUSION

For the foregoing reasons, Plaintiffs' motion to partially exclude the opinions of Dr. Lauren Stiroh should be denied.

Dated: June 2, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 2, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

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